



PATENT
Docket No.: 20747/270 (ARDBW/P29257US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | | |
|------------|---|---|---|----------------|
| Applicant | : | Axel Thomson |) | Examiner: |
| Serial No. | : | 10/528,267 |) | To Be Assigned |
| Cnfrm. No. | : | To Be Assigned |) | Art Unit: |
| Filed | : | September 17, 2003 |) | To Be Assigned |
| For | : | A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT |) | |

RECEIVED
JAN 20 2006
TECH CENTER 1600/2900

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97-1.98

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§ 1.97-1.98, applicant hereby brings to the attention of the United States Patent and Trademark Office, the enclosed references listed on the attached PTO/SB/08 form.

Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. Patents (i.e., Reference Cite Nos. 1-2) are not enclosed. Copies of all other listed references (i.e., Reference Cite Nos. 3-67) are enclosed herewith.

Pursuant to 37 CFR § 1.97(b)(3), no fee is required. If additional fees are required, however, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 14-1138.

Respectfully submitted,

Date: August 29, 2005

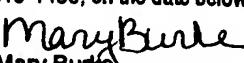

Edwin V. Merkel

Registration No. 49,087

Certificate of Mailing - 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450, on the date below.

Date 8/30/05


Mary Burke

NIXON PEABODY LLP
Clinton Square, P.O. Box 31051
Rochester, New York 14603-1051
Telephone: (585) 263-1128
Facsimile: (585) 263-1600

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



| | | | | | |
|------------------------------|---|----|---|--------------------------|----------------------------|
| Institute for form 1449A/PTO | | | | <i>Complete if Known</i> | |
| | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 1 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

| U.S. PATENT DOCUMENTS | | | | | |
|---|-----------------------|---|--------------------------------|--|---|
| Examiner Initials ¹ | Cite No. ¹ | U.S. Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number - Kind Code ² (<i>if known</i>) | | | |
| 1 | US-4,946,779 | 08-07-1990 | Kameda et al. | | |
| 2 | US-6,291,516 B1 | 09-18-2001 | Dudek et al. | | |
| | US- | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | |
| Examiner Initials ¹ | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Country Code ³ Number ⁴ Kind Code ³ (<i>if known</i>) | | | |
| 3 | WO 99/52534 A1 | 10-21-1999 | Beachy et al. | | |
| 4 | WO 00/41545 A1 | 07-20-2000 | Dudek | | |
| 5 | WO 01/27135 A2 | 04-19-2001 | Beachy | | |
| 6 | WO 02/30462 A2 | 04-18-2002 | Dudek et al. | | |
| 7 | WO 02/36818 A2 | 05-10-2002 | Martin et al. | | |
| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | | |
| Examiner Initials ¹ | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | T ⁶ |
| | 8 | ABRAHAMS et al., "Validation of Cytokeratin 5/6 as an Effective Substitute for keratin 903 in the Differentiation of Benign from Malignant Glands in Prostate Needle Biopsies," <i>Histopathology</i> 41:35-41 (2002) | | | |
| | 9 | BELLUSCI et al., "Fibroblast Growth Factor 10 (FGF10) and Branching Morphogenesis in the Embryonic Mouse Lung," <i>Development</i> 124:4867-4878 (1997) | | | |
| | 10 | BELLUSCI et al., "Involvement of Sonic Hedgehog (<i>Shh</i>) in Mouse Embryonic Lung Growth and Morphogenesis," <i>Development</i> 124:53-63 (1997) | | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|-------------------------------|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Group Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 2 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | | |
|---|-----------------------|---|--|--|--|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | |
| | 11 | BHATIA-GAUR et al., "Roles for <i>Nlx3.1</i> in Prostate Development and Cancer," <i>Genes Dev.</i> 13:966-977 (1999) | | | |
| | 12 | BITGOOD & McMAHON, "Hedgehog and <i>Bmp</i> Genes Are Coexpressed at Many Diverse Sites of Cell-Cell Interaction in the Mouse Embryo," <i>Dev. Biol.</i> 172:126-138 (1995) | | | |
| | 13 | BOSTWICK et al., "Prostatic Intra-Epithelial Neoplasia and Early Invasion in Prostate Cancer," <i>Cancer</i> 59:788-794 (1987) | | | |
| | 14 | CHEN et al., "Inhibition of Hedgehog Signaling by Direct Binding of Cyclopamine to Smoothened," <i>Genes Dev.</i> 16:2743-2748 (2002) | | | |
| | 15 | CHEN et al., "Small Molecule Modulation of Smoothened Activity," <i>Proc. Natl. Acad. Sci. USA</i> 99(22):14071-14076 (2002) | | | |
| | 16 | CHIANG et al., "Cyclopia and Defective Axial Patterning in Mice Lacking <i>Sonic Hedgehog</i> Gene Function," <i>Nature</i> 383:407-413 (1996) | | | |
| | 17 | CHIANG et al., "Essential Role for <i>Sonic hedgehog</i> During Hair Follicle Morphogenesis," <i>Dev. Biol.</i> 205:1-9 (1999) | | | |
| | 18 | CHOMCZYNSKI et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction," <i>Anal. Biochem.</i> 162:156-159 (1987) | | | |
| | 19 | COLE et al., "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer," <i>Monoclonal Antibodies and Cancer Therapy</i> , Alan R. Liss, Inc., pp.77-96 (1985) | | | |
| | 20 | COTE et al., "Generation of Human Monoclonal Antibodies Reactive with Cellular Antigens," <i>Proc. Natl. Acad. Sci. USA</i> 80:2026-2030 (1983) | | | |
| | 21 | CUNHA & CHUNG, "Stromal-Epithelial Interactions-I. Induction of Prostatic Phenotype in Urothelium of Testicular Feminized (Tfm/y) Mice," <i>J. Steroid Biochem.</i> 14:1317-1321 (1981) | | | |
| | 22 | CUNHA et al., "Smooth Muscle-Epithelial Interactions in Normal and Neoplastic Prostatic Development," <i>Acta Anat.</i> 155:63-72 (1996) | | | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|-------------------------------|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Group Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 3 | of | 6 | Attorney Docket Number | 20747/270 (ARDWB/P29257US) |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|---|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 23 | EPSTEIN, J.I., "Nonspecific Granulomatous Prostatitis vs. Infectious Granulomas," in <i>Differential Diagnosis in Pathology: Urologic Disorders</i> , Section 3: Prostate, New York, Igaku-Shoin Ltd., pp.74-136 (1992) | | |
| | 24 | FREEMAN et al., "A Comparison of Basal Cell Markers Used in the Prostate," <i>Histopathology</i> 40:483-494 (2002) | | |
| | 25 | FROHMAN et al., "Isolation of the Mouse <i>Hox-2.9</i> Gene; Analysis of Embryonic Expression Suggests that Positional Information Along the Anterior-Posterior Axis is Specified by Mesoderm," <i>Development</i> 110:589-607 (1990) | | |
| | 26 | GAO et al., "Conversion from a Paracrine to an Autocrine Mechanism of Androgen-Stimulated Growth during Malignant Transformation of Prostatic Epithelial Cells," <i>Cancer Res.</i> 61:5038-5044 (2001) | | |
| | 27 | GENBANK ACCESSION NO. U43148 (1996) | | |
| | 28 | GENBANK ACCESSION NO. L38518 (1995) | | |
| | 29 | GENBANK ACCESSION NO. U84401 (1997) | | |
| | 30 | GENBANK ACCESSION NO. AF316573 (2002) | | |
| | 31 | GENBANK ACCESSION NO. AB007298 (2002) | | |
| | 32 | GENBANK ACCESSION NO. M57609 (1994) | | |
| | 33 | HARAGUCHI et al., "Unique Functions of Sonic Hedgehog Signaling During External Genitalia Development," <i>Development</i> 128:4241-4250 (2001) | | |
| | 34 | HAYWARD et al., "Epithelial Development in the Rat Ventral Prostate, Anterior Prostate and Seminal Vesicle," <i>Acta Anat.</i> 155:81-93 (1996) | | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|-------------------------------|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Group Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 4 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | | |
|---|-----------------------|---|--|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | |
| | 35 | HAYWARD et al., "Interactions Between Adult Human Prostatic Epithelium and Rat Urogenital Sinus Mesenchyme in a Tissue Recombination Model," <i>Differentiation</i> 63:131-140 (1998) | | | T ² |
| | 36 | INCARDONA et al., "The Teratogenic <i>Veratrum</i> Alkaloid Cyclopamine Inhibits Sonic Hedgehog Signal Transduction," <i>Development</i> 125:3553-3562 (1998) | | | |
| | 37 | KIM et al., " <i>Nkx3.1</i> Mutant Mice Recapitulate Early Stages of Prostate Carcinogenesis," <i>Cancer Res.</i> 62:2999-3004 (2002) | | | |
| | 38 | KIM et al., "Pancreas Development is Promoted by Cyclopamine, a Hedgehog Signaling Inhibitor," <i>Proc. Natl. Acad. Sci. USA</i> 95:13036-13041 (1998) | | | |
| | 39 | KÖHLER & MILSTEIN, "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity," <i>Nature</i> 256:495-497 (1975) | | | |
| | 40 | KOZBOR & RODER, "The Production of Monoclonal Antibodies from Human Lymphocytes," <i>Immunol. Today</i> 4(3):72-79 (1983) | | | |
| | 41 | LAMM et al., "Mesenchymal Factor Bone Morphogenetic Protein 4 Restricts Ductal Budding and Branching Morphogenesis in the Developing Prostate," <i>Dev. Biol.</i> 232:301-314 (2001) | | | |
| | 42 | LAMM et al., "Sonic Hedgehog Activates Mesenchymal <i>Gli1</i> Expression during Prostate Ductal Bud Formation," <i>Dev. Biol.</i> 249:349-366 (2002) | | | |
| | 43 | MORRISON et al., "Chimeric Human Antibody Molecules: Mouse Antigen-Binding Domains with Human Constant Region Domains," <i>Proc. Natl. Acad. Sci. USA</i> 81:6851-6855 (1984) | | | |
| | 44 | NEUBERGER et al., "Recombinant Antibodies Possessing Novel Effector Functions," <i>Nature</i> 312:604-608 (1984) | | | |
| | 45 | NOGAWA et al., "Bud Formation Precedes the Appearance of Differential Cell Proliferation During Branching Morphogenesis of Mouse Lung Epithelium In Vitro," <i>Dev. Dyn.</i> 213:228-235 (1998) | | | |
| | 46 | OLUMI et al., "Carcinoma-Associated Fibroblasts Direct Tumor Progression of Initiated Human Prostatic Epithelium," <i>Cancer Res.</i> 59:5002-5011 (1999) | | | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|-------------------------------|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Group Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 5 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | |
|---|-----------------------|---|----------------|
| Examiner Initials ¹ | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | 47 | ORLANDI et al., "Cloning Immunoglobulin Variable Domains for Expression by the Polymerase Chain Reaction," <i>Proc. Natl. Acad. Sci. USA</i> 86:3833-3837 (1989) | |
| | 48 | PARSONS et al., "p63 Protein Expression is Rare I Prostate Adenocarcinoma: Implications for Cancer Diagnosis and Carcinogenesis," <i>Urology</i> 58:619-624 (2001) | |
| | 49 | PATHI et al., "Comparative Biological Responses to Human Sonic, Indian, and Desert Hedgehog," <i>Mech. Dev.</i> 106:107-117 (2001) | |
| | 50 | PEPICELLI et al., "Sonic Hedgehog Regulates Branching Morphogenesis in the Mammalian Lung," <i>Curr. Biol.</i> 8:1083-1086 (1998) | |
| | 51 | PERRITON et al., "Sonic hedgehog Signaling from the Urethral Epithelium Controls External Genital Development," <i>Dev. Biol.</i> 247:26-46 (2002) | |
| | 52 | RAMALHO-SANTOS et al., "Hedgehog Signals Regulate Multiple Aspects of Gastrointestinal Development," <i>Development</i> 127:2763-2772 (2000) | |
| | 53 | ROELINK et al., "Floor Plate and Motor Neuron Induction by <i>vhh-1</i> , a Vertebrate Homolog of <i>hedgehog</i> Expressed by the Notochord," <i>Cell</i> 76:761-775 (1994) | |
| | 54 | RUIZ I ALTABA et al., "Gli and Hedgehog in Cancer: Tumours, Embryos and Stem Cells," <i>Nat. Rev. Cancer</i> 2:361-372 (2002) | |
| | 55 | SCHNEIDER et al., "Targeted Disruption of the Nkx3.1 Gene in Mice Results in Morphogenetic Defects of Minor Salivary Glands: Parallels to Glandular Duct Morphogenesis in Prostate," <i>Mech. Dev.</i> 95:163-174 (2000) | |
| | 56 | STONE et al., "The Tumour-Suppressor Gene <i>Patched</i> Encodes a Candidate Receptor for Sonic Hedgehog," <i>Nature</i> 384:129-134 (1996) | |
| | 57 | SUGIMURA et al., "Keratinocyte Growth Factor (KGF) Can Replace Testosterone in the Ductal Branching Morphogenesis of the Rat Ventral Prostate," <i>Int. J. Dev. Biol.</i> 40:941-951 (1996) | |
| | 58 | SUGIMURA et al., "Morphogenesis of Ductal Networks in the Mouse Prostate," <i>Biol. Reprod.</i> 34:961-971 (1986) | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

¹ EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

² Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|-------------------------------|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Group Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 6 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | | |
|---|-----------------------|---|--|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | T ² |
| | 59 | SUKEGAWA et al., "The Concentric Structure of the Developing Gut is Regulated by Sonic Hedgehog Derived from Endodermal Epithelium," <i>Development</i> 127:1971-1980 (2000) | | | |
| | 60 | TAKEDA et al., "Construction of Chimaeric Processed Immunoglobulin Genes Containing Mouse Variable and Human Constant Region Sequences," <i>Nature</i> 314:452-454 (1985) | | | |
| | 61 | THOMSON & CUNHA, "Prostatic Growth and Development are Regulated by FGF10," <i>Development</i> 126:3693-3701 (1999) | | | |
| | 62 | THOMSON et al., "Analysis of Growth Factor and Receptor mRNA Levels During Development of the Rat Seminal Vesicle and Prostate," <i>Development</i> 124:2431-2439 (1997) | | | |
| | 63 | THOMSON et al., "The Role of Smooth Muscle in Regulating Prostatic Induction," <i>Development</i> 129:1905-1912 (2002) | | | |
| | 64 | TOTTEN et al., "Microscopic Differential Diagnosis of Latent Carcinoma of Prostate," <i>Arch. Pathol.</i> 55:131-141 (1953) | | | |
| | 65 | WANG et al., "Cell Differentiation Lineage in the Prostate," <i>Differentiation</i> 68:270-279 (2001) | | | |
| | 66 | WINTER & MILSTEIN, "Man-made Antibodies," <i>Nature</i> 349:293-299 (1991) | | | |
| | 67 | WOJNO et al., "The Utility of Basal Cell-Specific Anti-Cytokeratin Antibody (34 β E12) in the Diagnosis of Prostate Cancer," <i>Am. J. Surg. Pathol.</i> 19(3):251-260 (1995) | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|-------------------------------|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449A/PTO | | | | <i>Complete if Known</i> | |
| | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 1 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

U.S. PATENT DOCUMENTS

| Examiner Initials ¹ | Cite No. ¹ | U.S. Patent Document | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------------------|-----------------------|---|---|--------------------------------|--|---|
| | | Number - Kind Code ² (<i>if known</i>) | Number - Kind Code ² (<i>if known</i>) | | | |
| 1 | US-4,946,779 | US-4,946,779 | 08-07-1990 | Kameda et al. | | |
| 2 | US-6,291,516 B1 | US-6,291,516 B1 | 09-18-2001 | Dudek et al. | | |
| | US- | | | | | |
| | US- | | | | | |
| | US- | | | | | |
| | US- | | | | | |
| | US- | | | | | |
| | US- | | | | | |
| | US- | | | | | |
| | US- | | | | | |
| | US- | | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials ¹ | Cite No. ¹ | Foreign Patent Document | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|--------------------------------|-----------------------|---|--|--------------------------------|--|---|----------------|
| | | Country Code ³ Number ⁴ | Kind Code ² (<i>if known</i>) | | | | |
| 3 | WO 99/52534 A1 | WO 99/52534 | A1 | 10-21-1999 | Beachy et al. | | |
| 4 | WO 00/41545 A1 | WO 00/41545 | A1 | 07-20-2000 | Dudek | | |
| 5 | WO 01/27135 A2 | WO 01/27135 | A2 | 04-19-2001 | Beachy | | |
| 6 | WO 02/30462 A2 | WO 02/30462 | A2 | 04-18-2002 | Dudek et al. | | |
| 7 | WO 02/36818 A2 | WO 02/36818 | A2 | 05-10-2002 | Martin et al. | | |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials ¹ | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------------------|-----------------------|---|----------------|
| | 8 | ABRAHAMS et al., "Validation of Cytokeratin 5/6 as an Effective Substitute for keratin 903 in the Differentiation of Benign from Malignant Glands in Prostate Needle Biopsies," <i>Histopathology</i> 41:35-41 (2002) | |
| | 9 | BELLUSCI et al., "Fibroblast Growth Factor 10 (FGF10) and Branching Morphogenesis in the Embryonic Mouse Lung," <i>Development</i> 124:4867-4878 (1997) | |
| | 10 | BELLUSCI et al., "Involvement of Sonic Hedgehog (<i>Shh</i>) in Mouse Embryonic Lung Growth and Morphogenesis," <i>Development</i> 124:53-63 (1997) | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Group Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 2 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|---|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 11 | BHATIA-GAUR et al., "Roles for <i>Nlx3.1</i> in Prostate Development and Cancer," <i>Genes Dev.</i> 13:966-977 (1999) | | |
| | 12 | BITGOOD & McMAHON, "Hedgehog and <i>Bmp</i> Genes Are Coexpressed at Many Diverse Sites of Cell-Cell Interaction in the Mouse Embryo," <i>Dev. Biol.</i> 172:126-138 (1995) | | |
| | 13 | BOSTWICK et al., "Prostatic Intra-Epithelial Neoplasia and Early Invasion in Prostate Cancer," <i>Cancer</i> 59:788-794 (1987) | | |
| | 14 | CHEN et al., "Inhibition of Hedgehog Signaling by Direct Binding of Cyclopamine to Smoothened," <i>Genes Dev.</i> 16:2743-2748 (2002) | | |
| | 15 | CHEN et al., "Small Molecule Modulation of Smoothened Activity," <i>Proc. Natl. Acad. Sci. USA</i> 99(22):14071-14076 (2002) | | |
| | 16 | CHIANG et al., "Cyclopia and Defective Axial Patterning in Mice Lacking <i>Sonic Hedgehog</i> Gene Function," <i>Nature</i> 383:407-413 (1996) | | |
| | 17 | CHIANG et al., "Essential Role for <i>Sonic hedgehog</i> During Hair Follicle Morphogenesis," <i>Dev. Biol.</i> 205:1-9 (1999) | | |
| | 18 | CHOMCZYNSKI et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction," <i>Anal. Biochem.</i> 162:156-159 (1987) | | |
| | 19 | COLE et al., "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer," <i>Monoclonal Antibodies and Cancer Therapy</i> , Alan R. Liss, Inc., pp.77-96 (1985) | | |
| | 20 | COTE et al., "Generation of Human Monoclonal Antibodies Reactive with Cellular Antigens," <i>Proc. Natl. Acad. Sci. USA</i> 80:2026-2030 (1983) | | |
| | 21 | CUNHA & CHUNG, "Stromal-Epithelial Interactions-I. Induction of Prostatic Phenotype in Urothelium of Testicular Feminized (Tfm/y) Mice," <i>J. Steroid Biochem.</i> 14:1317-1321 (1981) | | |
| | 22 | CUNHA et al., "Smooth Muscle-Epithelial Interactions in Normal and Neoplastic Prostatic Development," <i>Acta Anat.</i> 155:63-72 (1996) | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

| | | | | | |
|--|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Group Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 3 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | | | |
|---|-----------------------|---|--|--|----------------|
| Examiner Initials ¹ | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | T ² |
| | 23 | EPSTEIN, J.I., "Nonspecific Granulomatous Prostatitis vs. Infectious Granulomas," in <i>Differential Diagnosis in Pathology: Urologic Disorders</i> , Section 3: Prostate, New York, Igaku-Shoin Ltd., pp.74-136 (1992) | | | |
| | 24 | FREEMAN et al., "A Comparison of Basal Cell Markers Used in the Prostate," <i>Histopathology</i> 40:483-494 (2002) | | | |
| | 25 | FROHMAN et al., "Isolation of the Mouse <i>Hox-2.9</i> Gene; Analysis of Embryonic Expression Suggests that Positional Information Along the Anterior-Posterior Axis is Specified by Mesoderm," <i>Development</i> 110:589-607 (1990) | | | |
| | 26 | GAO et al., "Conversion from a Paracrine to an Autocrine Mechanism of Androgen-Stimulated Growth during Malignant Transformation of Prostatic Epithelial Cells," <i>Cancer Res.</i> 61:5038-5044 (2001) | | | |
| | 27 | GENBANK ACCESSION NO. U43148 (1996) | | | |
| | 28 | GENBANK ACCESSION NO. L38518 (1995) | | | |
| | 29 | GENBANK ACCESSION NO. U84401 (1997) | | | |
| | 30 | GENBANK ACCESSION NO. AF316573 (2002) | | | |
| | 31 | GENBANK ACCESSION NO. AB007298 (2002) | | | |
| | 32 | GENBANK ACCESSION NO. M57609 (1994) | | | |
| | 33 | HARAGUCHI et al., "Unique Functions of Sonic Hedgehog Signaling During External Genitalia Development," <i>Development</i> 128:4241-4250 (2001) | | | |
| | 34 | HAYWARD et al., "Epithelial Development in the Rat Ventral Prostate, Anterior Prostate and Seminal Vesicle," <i>Acta Anat.</i> 155:81-93 (1996) | | | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|-------------------------------|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Group Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 4 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|---|--|----------------|
| Examiner Initials ¹ | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | |
| | 35 | HAYWARD et al., "Interactions Between Adult Human Prostatic Epithelium and Rat Urogenital Sinus Mesenchyme in a Tissue Recombination Model," <i>Differentiation</i> 63:131-140 (1998) | | T ² |
| | 36 | INCARDONA et al., "The Teratogenic <i>Veratrum</i> Alkaloid Cyclopamine Inhibits Sonic Hedgehog Signal Transduction," <i>Development</i> 125:3553-3562 (1998) | | |
| | 37 | KIM et al., " <i>Nkx3.1</i> Mutant Mice Recapitulate Early Stages of Prostate Carcinogenesis," <i>Cancer Res.</i> 62:2999-3004 (2002) | | |
| | 38 | KIM et al., "Pancreas Development is Promoted by Cyclopamine, a Hedgehog Signaling Inhibitor," <i>Proc. Natl. Acad. Sci. USA</i> 95:13036-13041 (1998) | | |
| | 39 | KÖHLER & MILSTEIN, "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity," <i>Nature</i> 256:495-497 (1975) | | |
| | 40 | KOZBOR & RODER, "The Production of Monoclonal Antibodies from Human Lymphocytes," <i>Immunol. Today</i> 4(3):72-79 (1983) | | |
| | 41 | LAMM et al., "Mesenchymal Factor Bone Morphogenetic Protein 4 Restricts Ductal Budding and Branching Morphogenesis in the Developing Prostate," <i>Dev. Biol.</i> 232:301-314 (2001) | | |
| | 42 | LAMM et al., "Sonic Hedgehog Activates Mesenchymal <i>Gli1</i> Expression during Prostate Ductal Bud Formation," <i>Dev. Biol.</i> 249:349-366 (2002) | | |
| | 43 | MORRISON et al., "Chimeric Human Antibody Molecules: Mouse Antigen-Binding Domains with Human Constant Region Domains," <i>Proc. Natl. Acad. Sci. USA</i> 81:6851-6855 (1984) | | |
| | 44 | NEUBERGER et al., "Recombinant Antibodies Possessing Novel Effector Functions," <i>Nature</i> 312:604-608 (1984) | | |
| | 45 | NOGAWA et al., "Bud Formation Precedes the Appearance of Differential Cell Proliferation During Branching Morphogenesis of Mouse Lung Epithelium In Vitro," <i>Dev. Dyn.</i> 213:228-235 (1998) | | |
| | 46 | OLUMI et al., "Carcinoma-Associated Fibroblasts Direct Tumor Progression of Initiated Human Prostatic Epithelium," <i>Cancer Res.</i> 59:5002-5011 (1999) | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Group Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 5 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|---|--|----------------|
| Examiner Initials ¹ | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | 47 | ORLANDI et al., "Cloning Immunoglobulin Variable Domains for Expression by the Polymerase Chain Reaction," <i>Proc. Natl. Acad. Sci. USA</i> 86:3833-3837 (1989) | | |
| | 48 | PARSONS et al., "p63 Protein Expression is Rare I Prostate Adenocarcinoma: Implications for Cancer Diagnosis and Carcinogenesis," <i>Urology</i> 58:619-624 (2001) | | |
| | 49 | PATHI et al., "Comparative Biological Responses to Human Sonic, Indian, and Desert Hedgehog," <i>Mech. Dev.</i> 106:107-117 (2001) | | |
| | 50 | PEPICELLI et al., "Sonic Hedgehog Regulates Branching Morphogenesis in the Mammalian Lung," <i>Curr. Biol.</i> 8:1083-1086 (1998) | | |
| | 51 | PERRITON et al., "Sonic hedgehog Signaling from the Urethral Epithelium Controls External Genital Development," <i>Dev. Biol.</i> 247:26-46 (2002) | | |
| | 52 | RAMALHO-SANTOS et al., "Hedgehog Signals Regulate Multiple Aspects of Gastrointestinal Development," <i>Development</i> 127:2763-2772 (2000) | | |
| | 53 | ROELINK et al., "Floor Plate and Motor Neuron Induction by <i>vhh-1</i> , a Vertebrate Homolog of <i>hedgehog</i> Expressed by the Notochord," <i>Cell</i> 76:761-775 (1994) | | |
| | 54 | RUIZ I ALTABA et al., "Gli and Hedgehog in Cancer: Tumours, Embryos and Stem Cells," <i>Nat. Rev. Cancer</i> 2:361-372 (2002) | | |
| | 55 | SCHNEIDER et al., "Targeted Disruption of the <i>Nlx3.1</i> Gene in Mice Results in Morphogenetic Defects of Minor Salivary Glands: Parallels to Glandular Duct Morphogenesis in Prostate," <i>Mech. Dev.</i> 95:163-174 (2000) | | |
| | 56 | STONE et al., "The Tumour-Suppressor Gene <i>Patched</i> Encodes a Candidate Receptor for Sonic Hedgehog," <i>Nature</i> 384:129-134 (1996) | | |
| | 57 | SUGIMURA et al., "Keratinocyte Growth Factor (KGF) Can Replace Testosterone in the Ductal Branching Morphogenesis of the Rat Ventral Prostate," <i>Int. J. Dev. Biol.</i> 40:941-951 (1996) | | |
| | 58 | SUGIMURA et al., "Morphogenesis of Ductal Networks in the Mouse Prostate," <i>Biol. Reprod.</i> 34:961-971 (1986) | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

¹ EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|----|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Application Number | 10/528,267 |
| | | | | Filing Date | September 17, 2003 |
| | | | | First Named Inventor | Axel Thomson |
| | | | | Group Art Unit | To Be Assigned |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 6 | of | 6 | Attorney Docket Number | 20747/270 (ARDBW/P29257US) |

| OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS | | | | |
|---|-----------------------|---|--|--|
| Examiner Initials ¹ | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | |
| | 59 | SUKEGAWA et al., "The Concentric Structure of the Developing Gut is Regulated by Sonic Hedgehog Derived from Endodermal Epithelium," <i>Development</i> 127:1971-1980 (2000) | | |
| | 60 | TAKEDA et al., "Construction of Chimaeric Processed Immunoglobulin Genes Containing Mouse Variable and Human Constant Region Sequences," <i>Nature</i> 314:452-454 (1985) | | |
| | 61 | THOMSON & CUNHA, "Prostatic Growth and Development are Regulated by FGF10," <i>Development</i> 126:3693-3701 (1999) | | |
| | 62 | THOMSON et al., "Analysis of Growth Factor and Receptor mRNA Levels During Development of the Rat Seminal Vesicle and Prostate," <i>Development</i> 124:2431-2439 (1997) | | |
| | 63 | THOMSON et al., "The Role of Smooth Muscle in Regulating Prostatic Induction," <i>Development</i> 129:1905-1912 (2002) | | |
| | 64 | TOTTEN et al., "Microscopic Differential Diagnosis of Latent Carcinoma of Prostate," <i>Arch. Pathol.</i> 55:131-141 (1953) | | |
| | 65 | WANG et al., "Cell Differentiation Lineage in the Prostate," <i>Differentiation</i> 68:270-279 (2001) | | |
| | 66 | WINTER & MILSTEIN, "Man-made Antibodies," <i>Nature</i> 349:293-299 (1991) | | |
| | 67 | WOJNO et al., "The Utility of Basal Cell-Specific Anti-Cytokeratin Antibody (34 β E12) in the Diagnosis of Prostate Cancer," <i>Am. J. Surg. Pathol.</i> 19(3):251-260 (1995) | | |
| | | | | |
| | | | | |
| | | | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.